K133509

510 (k) Summary

FEB 21 2014

1. Submitter Information

Company name: Biotest Medical Corporation

Contact person: Fred Lee

Address: No. 3-2 , Chien-kuo road, TEPZ Tantzu, 427, Taichung, Taiwan

Phone: 886-4-2532-6668

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2. Name of Device

Trade Name: Easy Plus II Blood Glucose Monitoring System, Model 6276-S
Easy Plus II Multi Blood Glucose Monitoring System, Model 6276-M
Smartest Persona II Blood Glucose Monitoring System, Model 6276-S
Smartest Persona II Multi Blood Glucose Monitoring System, Model 6276-M

Common Names: In Vitro Diagnostic Glucose Test System

Product Code: NBW, System, Test, Blood Glucose, Over-the-Counter & Prescription.
CGA, Glucose Oxidase, Glucose
JJX, Quality Control Material

Classification Panel: Clinical Chemistry

Device Class: Class II (21 CFR 862.1345)

3. Predicate Device

Trade Name: Easy Talk Blood Glucose Monitoring System, Model 6277

Common Name: In Vitro Diagnostic Glucose Test System

Submitter: Biotest Medical Corporation

510 (k) Number: K100560

4. Device Description

The Easy Plus II Blood Glucose Monitoring System, Model 6276-S (also applicable to: Easy Plus II Multi Blood Glucose Monitoring System, Model 6276-M; Smartest Persona II Blood Glucose Monitoring System, Model 6276-S; Smartest Persona II Multi Blood Glucose Monitoring System, Model 6276-M) is a product kit consisting of a blood glucose meter, test strips, control solutions, a lancing device, lancets, and instructions for use. The data download functionality is optionally available and sold separately.

To perform a test, a glucose test strip is inserted into the top of the device. When a small drop of blood is applied to the end of the test strip, glucose reacts with the

reagents on the test strip, producing an electrical current that is proportional to the blood glucose concentration. The glucose concentration is calculated by the glucose meter and is based on the electrical current measured. The quantitative glucose concentration (in mg/dL or mmol/L) is displayed on the display screen.

5. Intended Use/Indications for Use

For single patient use

Easy Plus II Blood Glucose Monitoring System, Model 6276-S

The Easy Plus II Blood Glucose Monitoring System Model 6276-S is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood drawn from the finger and the forearm. The Easy Plus II Blood Glucose Monitoring System Model 6276-S is intended to be used by a single person and should not be shared.

The Easy Plus II Blood Glucose Monitoring System Model 6276-S is intended for self-testing outside the body(in vitro diagnostic use) by people with diabetes at home as an aid in monitoring the effectiveness of a diabetes control program. The Easy Plus II Blood Glucose Monitoring System Model 6276-S should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady state times (when glucose in not changing rapidly).

The Easy Plus II Test Strips are for use with the Easy Plus II Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood drawn from the finger and the forearm.

The Easy Plus II Control Solutions are for use with the Easy Plus II Blood Glucose Monitoring System Model 6276-S as a quality control check to verify that the meter and test strips are working together properly.

Smartest Persona II Blood Glucose Monitoring System, Model 6276-S

The Smartest Persona II Blood Glucose Monitoring System Model 6276-S is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood drawn from the finger and the forearm. The Smartest Persona II Blood Glucose Monitoring System Model 6276-S is intended to be used by a single person and should not be shared.

The Smartest Persona II Blood Glucose Monitoring System Model 6276-S is intended for self-testing outside the body(in vitro diagnostic use) by people with diabetes at home as an aid in monitoring the effectiveness of a diabetes control. The Smartest Persona II Blood Glucose Monitoring System Model 6276-S should not be used for the diagnosis of or screening of diabetes or for neonatal use.

Alternative site testing should be done only during steady state times (when glucose in not changing rapidly).

The Smartest Persona II Test Strips are for use with the Smartest Persona II Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood drawn from the finger and the forearm.

The Smartest Persona II Control Solutions are for use with the Smartest Persona II Blood Glucose Monitoring System Model 6276-S as a quality control check to verify that the meter and test strips are working together properly.

For multiple patient use

Easy Plus II Multi Blood Glucose Monitoring System, Model 6276-M

The Easy Plus II Multi Blood Glucose Monitoring System Model 6276-M is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood drawn from the finger and the forearm. The Easy Plus II Multi Blood Glucose Monitoring System Model 6276-M is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple-patient use in a profession healthcare setting as an aid to monitor the effectiveness of a diabetes control program. This system should only be used with single-use, auto-disabling lancets.

The Easy Plus II Multi Blood Glucose Monitoring System Model 6276-M should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady state times (when glucose in not changing rapidly).

The Easy Plus II Multi Test Strips are for use with the Easy Plus II Blood Glucose Multi Meter to quantitatively measure glucose in fresh capillary whole blood drawn from the finger and the forearm.

The Easy Plus II Multi Control Solutions are for use with the Easy Plus II Multi Blood Glucose Monitoring System Model 6276-M as a quality control check to verify that the meter and test strips are working together properly.

Smartest Persona II Multi Blood Glucose Monitoring System, Model 6276-M

The Smartest Persona II Multi Blood Glucose Monitoring System Model 6276-M is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood drawn from the finger and the forearm. The Smartest Persona II Multi Blood Glucose Monitoring System Model 6276-M is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple-patient use in a profession healthcare setting as an aid to monitor the effectiveness of a diabetes control program. This system should only be used with

single-use, auto-disabling lancets.

The Smartest Persona II Multi Blood Glucose Monitoring System Model 6276-M should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady state times (when glucose in not changing rapidly).

The Smartest Persona II Multi Test Strips are for use with the Smartest Persona II Blood Glucose Multi Meter to quantitatively measure glucose in fresh capillary whole blood drawn from the finger and the forearm.

The Smartest Persona II Multi Control Solutions are for use with the Smartest Persona II Multi Blood Glucose Monitoring System Model 6276-M as a quality control check to verify that the meter and test strips are working together properly.

6. Comparison to Predicate Device

Easy Plus II Blood Glucose Monitoring System (Model 6276-S, 6276-M)

For the proposed Easy Plus II (6276-S) and Easy Plus II Multi (6276-M) Blood Glucose Monitoring Systems, the modification from the cleared Easy Talk Blood Glucose Monitoring System, Model 6277 (K100560) include the following:

A. Voice feature change from talking to non-talking

This modification involves the removal of speaker component as well as talking software module from Easy Talk Blood Glucose Monitoring System (Model 6277). This modification was made due to customer's input and marketing consideration.

B. Modification of housing design

The housing of the device was slightly modified due to customer's input and marketing consideration. Except the removal of speaker component, no change was made to the materials used or to the internal elements of the device. The change was made for style purpose to differentiate it from its predicate with talking feature, Easy Talk Blood Glucose Monitoring System (Model 6277).

Easy Plus II (6276-S) and Easy Plus II Multi (6276-M) Blood Glucose Monitoring Systems, in all functions and specifications are exactly same as Easy Talk Blood Glucose Monitoring System (Model 6277) except for the talking feature and housing design. The modifications in talking feature and housing design will not affect the intended use of the device, and it will not significantly affect safety or effectiveness.

The modifications maintain the integrity of the Easy Plus II (6276-S) and Easy Plus II Multi (6276-M) as described in the original clearance in terms of the intended use

of the device (i.e., the quantitative measurement of glucose in capillary blood), and the fundamental scientific technology employed. Product sterilization, shelf-life, and biocompatibility are unaffected by the modifications and are equivalent to the legally marketed Easy Talk Blood Glucose Monitoring System, Model 6277 (K100560).

Smartest Persona II Blood Glucose Monitoring System (Model 6276-S, 6276-M)

For the proposed Smartest Persona II (6276-S) and Smartest Persona II Multi (6276-M) Blood Glucose Monitoring Systems, as the modifications are identical to those described above for the Easy Plus II (6276-S) and Easy Plus II Multi (6276-M) Blood Glucose Monitoring Systems and therefore not repeated here although the housing design of Smartest Persona II devices (Model 6276-S, 6276-M) is different from that of Easy Plus II devices (Model 6276-S, 6276-M) mainly in colors.

With the reasons outlined above, the Easy Plus II devices (Model 6276-S, 6276-M) and the Smartest Persona II devices (Model 6276-S, 6276-M) are eligible for Special 510(k) in accordance with FDA guidance.[1]

7. Performance Studies

Biotest Medical Corp. has conducted a risk analysis and has performed the necessary verification and validation activities to demonstrate that the design outputs of the modified devices, Easy Plus II (6276-S), Easy Plus II Multi (6276-M) Smartest Persona II (6276-S), and Smartest Persona II Multi (6276-M) meet the design input requirements.

Cleaning is the process of removing dirt or touch contaminants while disinfection is the process of killing viruses. Disinfection studies were performed on the meter and lancing device by a third party testing service to determine the disinfection efficacy of the meter to the recommended cleaning and disinfection procedure, and its effectiveness in preventing the spread of blood-borne pathogens, particularly hepatitis B virus (HBV). Clorox® Bleach Germicidal Wipes (EPA Reg No: 67619-12) was validated, demonstrating complete inactivation of live virus for use with the meters. The robustness studies were also conducted and demonstrated that there was no change in performance or in the external materials of the meters after 11,000 cycles of cleaning and 11,000 cycles of disinfection to simulate the claimed 3 year use life.

[1] Center for Devices and Radiological Health. *The New 510(k) Paradigm – Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications – Final Guidance*. March 20, 1998.

Lay user questionnaire: 20 lay users evaluated the ease of use of the devices and the presentation of the labeling. All users answered that Easy Plus II and Smartest Persona II Blood Glucose Monitoring Systems were very easy to use and the user manuals were written to make the devices easy to use.

8. Conclusion

Modifications to the cleared device, Easy Talk Blood Glucose Monitoring System, Model 6277 (K100560), include voice feature change from talking to non-talking and housing design. In summary, the Easy Plus II (6276-S), Easy Plus II Multi (6276-M), Smartest Persona II (6276-S), and Smartest Persona II Multi (6276-M) described in this submission are substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

BIOTEST MEDICAL CORP.
FRED LEE
ENGINEERING/REG. MANAGER
No. 3-2, CHIEN-KUO ROAD, TEPZ TANTZU,
427, TAICHUNG, TAIWAN

February 21, 2014

Re: k133509
Trade/Device Name: Easy Plus II Blood Glucose Monitoring System, Model 6276-S
Easy Plus II Multi Blood Glucose Monitoring System, Model 6276-M
Smartest Persona II Blood Glucose Monitoring System, Model 6276-S
Smartest Persona II Multi Blood Glucose Monitoring System, Model 6276-M
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, CGA, JJX
Dated: January 20, 2014
Received: January 22, 2014

Dear Mr. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements

as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ruth A. Chesler -S

for Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133509

Device Name
Easy Plus II Blood Glucose Monitoring System, Model 6276-S

Indications for Use *(Describe)*
The Easy Plus II Blood Glucose Monitoring System Model 6276-S is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood drawn from the finger and the forearm. The Easy Plus II Blood Glucose Monitoring System Model 6276-S is intended to be used by a single person and should not be shared. The Easy Plus II Blood Glucose Monitoring System Model 6276-S is intended for self-testing outside the body(in vitro diagnostic use) by people with diabetes at home as an aid in monitoring the effectiveness of a diabetes control program. The Easy Plus II Blood Glucose Monitoring System Model 6276-S should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady state times (when glucose in not changing rapidly).

The Easy Plus II Test Strips are for use with the Easy Plus II Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood drawn from the finger and the forearm.

The Easy Plus II Control Solutions are for use with the Easy Plus II Blood Glucose Monitoring System Model 6276-S as a quality control check to verify that the meter and test strips are working together properly.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

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Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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Food and Drug Administration

Indications for Use

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Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133509

Device Name
Easy Plus II Multi Blood Glucose Monitoring System, Model 6276-M

Indications for Use *(Describe)*
The Easy Plus II Multi Blood Glucose Monitoring System Model 6276-M is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood drawn from the finger and the forearm. The Easy Plus II Multi Blood Glucose Monitoring System Model 6276-M is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple-patient use in a profession healthcare setting as an aid to monitor the effectiveness of a diabetes control program. This system should only be used with single-use, auto-disabling lancets. The Easy Plus II Multi Blood Glucose Monitoring System Model 6276-M should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady state times (when glucose in not changing rapidly).

The Easy Plus II Multi Test Strips are for use with the Easy Plus II Blood Glucose Multi Meter to quantitatively measure glucose in fresh capillary whole blood drawn from the finger and the forearm.

The Easy Plus II Multi Control Solutions are for use with the Easy Plus II Multi Blood Glucose Monitoring System Model 6276-M as a quality control check to verify that the meter and test strips are working together properly.

Type of Use *(Select one or both, as applicable)*

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Indications for Use

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510(k) Number *(if known)*
K133509

Device Name
Smartest Persona II Blood Glucose Monitoring System, Model 6276-S

Indications for Use *(Describe)*
The Smartest Persona II Blood Glucose Monitoring System Model 6276-S is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood drawn from the finger and the forearm. The Smartest Persona II Blood Glucose Monitoring System Model 6276-S is intended to be used by a single person and should not be shared. The Smartest Persona II Blood Glucose Monitoring System Model 6276-S is intended for self-testing outside the body(in vitro diagnostic use) by people with diabetes at home as an aid in monitoring the effectiveness of a diabetes control. The Smartest Persona II Blood Glucose Monitoring System Model 6276-S should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady state times (when glucose in not changing rapidly).

The Smartest Persona II Test Strips are for use with the Smartest Persona II Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood drawn from the finger and the forearm.

The Smartest Persona II Control Solutions are for use with the Smartest Persona II Blood Glucose Monitoring System Model 6276-S as a quality control check to verify that the meter and test strips are working together properly.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Number *(if known)*
K133509

Device Name
Smartest Persona II Multi Blood Glucose Monitoring System, Model 6276-M

Indications for Use *(Describe)*
The Smartest Persona II Multi Blood Glucose Monitoring System Model 6276-M is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood drawn from the finger and the forearm. The Smartest Persona II Multi Blood Glucose Monitoring System Model 6276-M is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple-patient use in a profession healthcare setting as an aid to monitor the effectiveness of a diabetes control program. This system should only be used with single-use, auto-disabling lancets. The Smartest Persona II Multi Blood Glucose Monitoring System Model 6276-M should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady state times (when glucose in not changing rapidly).

The Smartest Persona II Multi Test Strips are for use with the Smartest Persona II Blood Glucose Multi Meter to quantitatively measure glucose in fresh capillary whole blood drawn from the finger and the forearm.

The Smartest Persona II Multi Control Solutions are for use with the Smartest Persona II Multi Blood Glucose Monitoring System Model 6276-M as a quality control check to verify that the meter and test strips are working together properly.

Type of Use *(Select one or both, as applicable)*

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